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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,398	07/17/2000	MELLENIE J MURPHY	124-781	4847

7590 02/27/2003

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EXAMINER
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HINES, JANA A

13

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/600,398

Applicant(s)

MURPHY ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) ~~1-35~~ 1-35, 37 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 21-35 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-20 is/are rejected.
- 7) ☒ Claim(s) 4-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Amendment Entry***

1. The amendment filed December 6, 2002 has been entered. Claims 4, 14 and 17 have been amended. Claims 4-20 are under consideration in this office action.

This application contains claims 1-3 and 21-35 and 37 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Withdrawal of Rejections***

2. The following rejections have been withdrawn in view of applicants' amendments:

a) the rejection of claims 4-16 under 35 U.S.C. 102(b) as being anticipated by Squirrell (WO 96/02666);

b) the rejection of claims 4-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

c) the rejection of claims 4-20 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps; and

d) the rejection of claims 4 and 17-20 under 35 U.S.C. 103(a) as being unpatentable over Squirrell (WO 96/02666) in view of Sanders (WO 94/064931).

***Response to Arguments***

3. Applicant's arguments filed December 6, 2002 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 4-20 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The claims are drawn to a method for determining the susceptibility of a bacteria to a reagent which method comprising a lysis steps, incubation steps, and comparison steps. However the claims fail to recite the addition of necessary reagents such as ATP, magnesium and the like. The steps fail to recite phage involvement which appears to be necessary to compare the susceptibility results. Moreover, the claims fail to recite any detection steps such as detecting luminescence or using the luminometer for detection.

The claims fail to positively recite all the assaying procedures and necessary reagents. Thus the claims fail to recite specifically how the assay of the culture is performed or what the results of the assays are. The specification teaches: exposing the appropriate bacterial cells to a reagent; subjecting the bacterial culture to lytic reagent

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so as to lyse the cells; extracting adenylate kinase from a sample; exposing the cells to any reagents necessary for assaying the adenylate kinase such as luciferin and if necessary separating the bacterial cells or preserving the cells and providing suitable growth media. See pages 8-12 of the instant specification. Figures 1,2, 3 and 7 all show luminescence as necessary to discern results. Figure 4 shows the results from a test with lytic and non-lytic antibiotic wherein each result analyzes the phage results.

The specification does not teach examples of said method comprised solely of the recited steps. Thus, merely reciting lysis and incubation steps in the claims without a reciting all the necessary steps does not provide enablement for the claimed method; neither does the recitation provide guidance on what the necessary reagents combinations are which will comprise a complete and accurate method of determination. The specification does not teach how to achieve a method for determining the susceptibility of a bacteria without the other necessary reagents and detection steps. Thus, the method recited in the claims does not teach the inclusion of the other necessary steps and reagents thus the claims are still rejected.

### ***New Grounds of Rejection***

#### ***Claim Objections***

5. Claims 4-20 are objected to because of the following informalities: Claim 4 steps (i)(a) uses the word "forma". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for comparing the sample of (i)(b) is greater than the amount of sample (ii) wherein the magnitude of such a difference being indicative of the degree of susceptibility of said bacteria to said reagent wherein a larger difference is indicative of greater susceptibility. Furthermore, neither the specification nor originally presented claims provides support for comparing measuring the amount of AK in a sample of (ii) is greater than the amount of AK present in sample of sample (i)(a) then the magnitude of the difference between the AK content of the sample of (ii) and (i)(a) indicates the degree of susceptibility of bacteria to said reagent wherein a smaller difference is indicative of greater susceptibility.

Applicant did not point to support in the specification for the comparison of the samples. Thus, there appears to be no teaching of the measured amount of AK present. Therefore, it appears that there is no support in the specification. Thus applicants must specifically point to page and line number support for the recited measurement analysis as recited by the newly added amendments. Therefore, the new claims incorporate new matter and are accordingly rejected.

7. Claims 4-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Step (i)(a) refers to lysing bacteria in the first and optional third sample. To form a lysed sample, however step (b) recites incubating and lysing the first or optional third sample. It is unclear how there are two first samples. Traditionally there is only one first sample, so that a first sample can only be treated in one way. Moreover, since the third sample is optional, there is no requirement that the third sample even be present. Thus the claims are unclear with respect to the treatment of the samples.

Likewise the measurement steps of (iii) are unclear.

8. Claim 14 is unclear. Claim 14 recites "A method according for determining...". This language is unclear and appropriate correction is required.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. the examiner can normally be reached on Monday-Thursday and alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers




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for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines   
February 12, 2003

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600